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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,495	12/05/2003	Richard B. Borgens	3220-73828	2575

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EXAMINER

MORRIS, PATRICIA L

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/730,495

Applicant(s)

BORGENS ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 3 and 4 are under consideration in this application.

#### *Election/Restrictions*

Again, this application has been examined with regard to the elected compounds wherein  $R^2$  represents  $-\text{COR}^3$ ,  $R^3$  is OR wherein R is a  $\text{C}_1\text{-C}_{20}$  alkyl group,  $R^6$  represents H, alkyl,  $\text{NO}_2$ , F, Cl, Br and I and  $R^1$ ,  $R^7\text{-}R^9$  as set forth in claim 3, exclusively. It is suggested that the nonelected compounds be deleted.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 4 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated by Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al for the reasons set forth in the previous Office action.

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Again, Czekaj et al. specifically disclose 3-iodo-4-pyridinyl, 1,1-dimethylethyl ester carbamic acid. Note example 9 [0201] therein.

Tulshian et al. recite the instant compound wherein  $R^7$  is Br,  $R^6$ ,  $R^8$  and  $R^9$  are hydrogen and  $R^3$  is tert-butoxy. Note example 18, column 16, line 55, therein.

Pauls et al. disclose the instant compounds wherein  $R^7$  is chlorine and  $R^6$  is either hydrogen or methyl. Note example 4 [0385] and [0387] therein.

Altenburger et al. specifically disclose 3,5-dibromo-4-pyridinyl-1,1-dimethylethyl ester carbamic acid. Note example 8 therein.

Ewing et al. disclose the instant compounds wherein the pyridine ring is substituted with chlorine or chlorine and iodine. Note example 247 A and B therein.

Bastian et al. disclose 3-methyl-4-pyridinyl)-1,1,-dimethylethyl ester carbamic acid. Note example 3, column 21, lines 33-34, therein.

Chen et al. specifically recite the instant compound wherein  $R^7$  represents chloro,  $R^8$  represents nitro and  $R^3$  is tert-butoxy.

Doll et al. and Clark-Lewis et al. specifically disclose the compound of claim 15 herein. Note preparative example 2 of Doll et al.

Tanga et al. disclose the instant compounds wherein the pyridine is substituted with methyl and  $R^3$  is methoxy. Note RN 193690-59-4, 193690-66-3, etc.

Takefuji et al. recite 3-chloro-2-ethyl-4-pyridinyl-,methyl ester carbamic acid. Note preparation example 4 therein.

Konishi et al. disclose the many of the instant compounds wherein R is alkyl. Note the tables of compounds recited on pages 4-5 therein.

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Shimizu et al. specifically disclose 2-chloro-4-pyridinyl-,propyl ester carbamic acid.

Note RN 121433-24-7.

Matondo et al. disclose the claimed methyl and dodecyl N-(4-pyridyl)carbamates.

Kiriazis et al. disclose the instant compound wherein R<sup>1</sup> is methyl and R is propyl. Note RN 125867-16-5.

Sakamoto et al. recite 3-bromo-4-pyridinyl-ethyl ester carbamic acid. Note RN 112671-56-4.

Von Bebenburg et al. specifically recite 2,6-dichloro-4-pyridinyl-ethyl ester carbamic acid. Note RN 73895-95-1.

Bickel et al. disclose the claimed compound wherein R is 1,1-dimethylpropyl. Note column 15, lines 31-32 therein.

Pews et al. and Imperial Chemical disclose the instant compounds wherein R is methyl, ethyl or propyl and R<sup>6</sup>-R<sup>9</sup> represent chlorine, fluorine or methyl. Note examples 3 and 4 of Pews et al. therein.

Yakhontov et al. specifically disclose 4-pyridinecarbamic acid, 3-ethyl ester, monohydrochloride. Note RN 19984-03-3.

Clark-Lewis and Takashi et al. teach the instant nitro substituted pyridines. Note RN 98279-90-4.

Contra to applicants' arguments in the instant response, the references teach pharmaceutical compositions containing the instant compounds. A pharmaceutical composition is nothing more than the compound plus an inert carrier.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1- 4 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. for the reasons set forth in the previous Office action.

As discussed supra, the references generically embrace the instant composition containing the compounds. Applicants appear to couch their arguments in terms of use. Yet

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applicants are merely claiming pharmaceutical compositions that contain the instant compounds.

As evidenced by the art of record, the instant compositions are obvious from the prior art.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, Claim 3 provides for the use of treating injured mammalian nerve tissue but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 3 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Contra to applicants' arguments in the instant response, applicants are claiming compositions. In order to overcome the rejection, the recitation of use needs to be deleted.

The plural 's' on salts makes claim 4 read on mixtures rather than specific compounds.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, the claims measure invention and resolution of invention must be based on what is claimed.

The C.C.P.A. in 1978 held that an invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claims. In re Priest, 199 USPQ 11, at 15.

### *Conclusion*

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

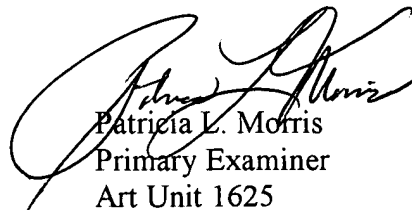
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris  
Primary Examiner  
Art Unit 1625

plm  
May 20, 2005